Before discussing the details of the Office Action, a brief discussion of the claimed invention is deemed helpful to understand the differences between the claimed invention and that of the prior art relied on in the Office Action. The claims of the present Application are directed to a chewing gum composition that is useful for removing stains on dental surfaces when placed in the oral cavity, and then chewed by the consumer. The chewing gum composition as claimed has two essential aspects, which in combination distinguish over the prior art.

The first aspect is that at least two stain removing components are employed in the chewing gum composition. These stain-removing components are selected from a peroxide compound, a polyphosphate, and an anionic surfactant. The second aspect is that the stain removing components must not be materially bound to the gum base, in order to achieve the objects of the invention. It is the combination of these two aspects that allows the applicants to achieve desirable stain-removing properties that are not obtained when only one stain-removing agent is employed, and/or when one or more of the stain-removing agents are materially bound to the gum base.

Page 19, lines 4-11 of the present Application, identifies the importance of enabling the release of the stain-removing agents from the chewing gum composition into the oral cavity. Several ways are provided for preventing the stain-removing agents from being materially bound to the gum base. As indicated at page 20, lines 4-10, the stain-removing agents can be added into the center-fill of a center-filled chewing gum composition, which does not contain gum base. Thus the stain-removing agent is kept

apart from the gum base, and therefore cannot become materially bound thereto. Another way of preventing undesirable binding of the stain-removing agents to the gum base is to place the stain-removing agents in the coating of a chewing gum composition containing a core and a coating, where the core contains the gum base.

However, many chewing gum compositions do not contain a hard coating or are not the center-fill variety. The problem is that when an anionic surfactant is added to such compositions, they serve as softeners to soften the gum base, making the chewing gum composition more "chewy". The prior art teaches that softeners are added directly to the gum base to provide the softening effect.

Thus, the present invention requires that the two or more stain-removing agents, regardless of where they are located, must not be materially bound to the gum base. If they are, they cannot be effectively released from the chewing gum composition to perform a stain-removing function, even though they anionic surfactants may effectively perform a "softening" function.

The present invention requires at least two stain-removing agents. Applicants have previously shown through reference to standard, well-accepted test procedures that there is an unexpectedly enhanced effect when two or more of the claimed stain-removing agents are incorporated into the chewing gum composition as compared to a single stain-removing agent. Page 4 of the Office Action questions the results presented in the Specification. First, the Office Action states that it cannot be

determined if the effects would also be seen when a chewing gum comprises the stain-removing components. Second, the results are alleged not to be commensurate in scope with the instant claims, since they use only a representative example of peroxide, an anionic surfactant and polyphosphate at specified amounts. Applicants respectfully traverse the criticism of the experimental data.

As previously indicated, one of the test procedures disclosed in the present Application, showing a stain-removing result, is a well-established protocol for this purpose. One of ordinary skill in the art would recognize that the procedure followed in the present Application is a valid indication of the stain-removing effect of the test compositions. These test compositions were used to treat stains appearing on hydroxyapatite discs (Examples 1 and 2). However, Example 3 provides a stain-removal test model in which gum samples containing the stain-removing composition were masticated by a chewing machine that was outfitted with stained bovine teeth, providing chewing surfaces to simulate the top and bottom teeth in a human mouth (page 37, lines 6-8). Accordingly, Applicants not only tested the stain-removing composition in a standard in vitro testing procedure, but also achieved the same results when utilizing the stain-removing composition within a chewing gum. Therefore, the criticism of the test results based on the disclosed experimental data is improper.

Applicants have explained in the Specification and during prosecution of the present Application that a key to the claimed invention is the availability of the stain-removing agents to perform a stain-removing function. To be available for this purpose,

the stain-removing agents must not be materially bound to the gum base. Applicants have provided several ways that this can be made possible in the manufacture of a chewing gum composition. Given that Applicants have taught how to construct how to construct a chewing gum composition with two or more of the claimed stain-removing agents, so that they are able to perform a stain-removing function, and given that the stain-removing agents must be available in a stain-removing effective amount, the examples shown in the present Application are clearly sufficient to prove efficacy of the claimed invention.

Applicants have provided examples of a stain-removing effective amount utilizing two or three of the stain-removing agents, and have shown surprising and unobvious results when compared with a control (water) and the use of only a single stain-removing agent. Applicants have used representative amounts of each of the components and certainly amounts that fit within the ranges provided in the dependent claims. Applicants are not required to demonstrate efficacy over the full possible range of the stain-removing agents unless there is a sound basis for doing so. The Office Action has presented no reason why one of ordinary skill in the art would not expect similar results with other stain-removing agents within the three categories of stain-removing agents set forth in claim 1.

It is therefore submitted that the surprising and unexpected use of two or more of the stain-removing agents set forth in the present claims, when used in a stain-removing effective amount, is sufficient to support the claims as they now stand. Unlike

unpredictable scientific disciplines such as cancer treatment, data presented in the present Application in support of a surprising and unobvious result would be expected for the full range of Applicants claims, in the absence of any evidence to the contrary.

As we have shown, the present invention relies on the combination of two or more stain-removing agents in effective amounts, and requires that they not be materially bound to the gum base. As we will further show, references relied on in the latest Office Action do not teach or suggest this combination of inventive aspects, nor would reasonable motivation or common knowledge enable one of ordinary skill in the art to reach the claimed invention.

Referring to the Day reference, the Office Action acknowledges that polyphosphates are distributed within the gum base, and indicates at page 11, lines 35-40, that the polymeric surface active agent is present in the gum base, the outer coating or both. Applicants do not disagree with this characterization of the reference. However, the Office Action appears to allege state that whitening agents and surfactants are active ingredients that are disclosed to be used in combination with the polymeric active material, and that such agents are not added to the gum base. The position taken in the Office Action is untenable.

Applicants have identified potassium stearate and sodium stearate (and their combination) as a preferred anionic surfactant for use in the present invention. These materials are identified in Day at page 8, lines 22-24, wherein it is stated that softeners

can be employed in chewing gum compositions, and that suitable softeners include sodium stearate and potassium stearate. Page 8, lines 32-34 clearly state that such materials are incorporated into the gum base in order to modify the texture and consistency properties of the gum base. "In particular, they help to soften the chew and to maintain chew softness over an extended period of time."

The preferred stain-removing agents of the present invention (sodium stearate and potassium stearate) are purposely incorporated into the gum base in the Day reference to provide a softening effect. One of ordinary skill in the art would recognize that anionic surfactants, and particularly sodium stearate and potassium stearate, have a softening function and would not know that such materials perform a stain-removing function. This is because when such substances are incorporated into the gum base, they are retained in the gum base and therefore, not available to perform a stain-removing function. It is only by Applicants discovery that when such substances are placed in the chewing gum composition in a manner that does not allow them to be materially bound to the gum base, that they are able to perform a stain removing function.

While Applicants agree that phosphates are disclosed and that they may be present in the core, the coating, or both, a fair reading of the Day reference teaches only that a single stain-removing agent may be used in the chewing gum composition. There is no teaching, however, of the use of two or more stain-removing agents, all of which are required to be out of contact with the gum base, and certainly no indication

that the use of two such stain-removing agents provides a surprising and unobvious stain-removing effect over the use of a single stain-removing agent.

The Howard reference is stated to teach a peroxyhydrate as a stain-removing agent. Thus, the Office Action admits that only one stain-removing agent is recognized in the Howard reference. The Office Action then presents the argument that the present invention mixes polyphosphates and anionic surfactants with the gum base and therefore manufactures the chewing gum composition in the same way as Howard. The rejection is hereby traversed, and reconsideration is respectfully requested.

The only one of the stain-removing components of the present invention disclosed in Howard is a peroxide compound (e.g. sodium carbonate peroxyhydrate). As indicated in column 4, lines 13-15, plasticizers or softening agents are incorporated *within* a gum base. Typical softeners/emulsifiers include glycerol triacetate, which is one of the anionic surfactants listed in claim 9 of the present Application. As shown in Example I, the Howard preparation of a chewing gum composition shows that the gum base is combined directly with the listed gum ingredients, which includes vegetable glycerin (a plasticizer or softening agent, column 4, line 14). Thus, the examples teach that a plasticizer or softening agent, including any anionic surfactants (e.g. glycerol tristearate) is added directly to the gum base.

Therefore, Howard teaches to one of ordinary skill in the art the use of a single stain-removing agent, and does not teach or suggest the use of two or more stain-

removing agents, nor the importance of keeping the stain-removing agents away from the gum base.

The Office Action suggests that the manner of incorporating the stain-removing agents into the chewing gum composition is the same as that in the Howard reference. This is clearly not correct. As we have shown, Howard incorporates emulsifiers/softeners directly into the gum base. The present Application, as previously explained, keeps the stain-removing agents in a different location than the gum base (e.g. in the center-fill or the coating where the gum base is not present, or mixes the stain-removing agent as one of the last steps, or preferably the last step, so that as much of the stain-removing agent is removed from the gum base as possible). Nothing in Howard teaches or suggests this aspect of the claimed invention.

Miskewitz teaches, like the other references, that conventional softeners, plastricizers and emulsifiers are added to the gum base. The Office Action alleges that surfactants are not necessarily used in the gum base, but provides no basis for reaching that conclusion. Instead, the Office Action looks to the present Application to allege that the compositions are made the same and therefore, the surfactant in the prior art is not materially bound to the gum base. This line of reasoning cannot be sustained. In observing the preparation of the product in Example III of the reference, a substantial portion of the urea peroxide is added directly to the gum base. This is contrary to the presently claimed invention. There is therefore no recognition in Miskewitz nor mention of the use of two or more stain-removing agents, each of which is <u>not</u> materially bound

to the gum base. The rejection based on Miskewitz is therefore improper and should be withdrawn.

Claims 20-24, 29 and 30 stand rejected as obvious over Day in view of Sagel (U.S. Patent No. 6,582,708). The rejection is hereby traversed and reconsideration is respectfully requested.

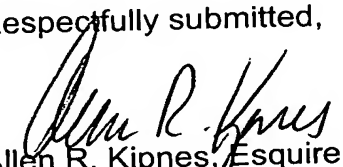
As previously indicated, the Office Action previously acknowledged that Sagel does not teach or suggest the use of a polyphosphate, or an anionic surfactant in the manner claimed in the present Application, to give a stain-removing effect. Since only the use of a peroxide compound is disclosed, there is no recognition of the surprising and unobvious nature of the present invention when employing two or more stain-removing agents. It is therefore submitted that Sagel does not add anything further to the disclosure of Day. The rejection based on obviousness is therefore unsupported, and should be withdrawn.

The rejection of claims 44-46 as obvious over Cherukuri (U. S. Patent No. 4,980,178) is noted, as is the application of this reference to claims 9-14, 24, 25 and 35. However, it has been established that Cherukuri is cited solely for the purpose that center-filled chewing gums were known in the art. As Applicants have previously shown, Day does not disclose the combination of stain-removing agents as required in the present claims, nor teach that all of the stain-removing agents must not be

materially bound to the gum base. It is therefore submitted that the claims rejected based on Day and Cherukuri are free of the prior art.

In view of the forgoing, Applicants submit that the present Application is in condition for Allowance, and early passage to issue is therefore deemed proper and is respectfully submitted.

Respectfully submitted,



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